



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/560,513

12/13/2005

Nathalie Marie-Josephe Garcon

VB60298

6380

20462 7590 05/02/2007
SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,513

Applicant(s)

GARCON ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35, 37, 39, 41-48, 51 and 53-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35, 37, 39, 41-48, 51 and 53-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-34, drawn to an immunogenic composition comprising a capsular polysaccharide or oligosaccharide of H.influenzae B (PRP) and a polyanionic polymer.

Group II, claim(s) 35, drawn to a method of treating or preventing H.influenzae B disease comprising administering a vaccine comprising an immunogenic composition comprising a capsular polysaccharide or oligosaccharide of H.influenzae B (PRP) and a polyanionic polymer and one or more further antigens.

Group III, claim(s) 37, 39 and 41-48, drawn to a method to reduce the immunological interference of a Haemophilus influenzae B capsular polysaccharide or oligosaccharide (PRP).

Group IV, claim(s) 51 and 53-58, drawn to a kit comprising a first immunogenic composition comprising a Haemophilus influenzae B capsular polysaccharide or oligosaccharide (PRP), and a polyanionic polymer; and ii) a second immunogenic composition comprising one or more antigens adsorbed onto an adjuvant with a zero point charge greater than 8.

Group V, claim(s) 59, drawn to an immunogenic composition comprising a saccharide antigen with pI less than 3, and a polyanionic polymer.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of Group I is not novel because Gupta et al (Biodegradable Polymer Microspheres as Vaccine Adjuvants and Delivery Systems" Dev. In Biol. Standardization. Karger, Basel CH, vol. 92, 1998, pages 63-78, teaching an immunogenic composition comprising a capsular polysaccharide or oligosaccharide of H.influenzae B (PRP) and a polyanionic polymer, e.g., Gupta teaches that a variety of vaccine antigens have been encapsulated in microspheres usually composed of poly (lactic/glycoli) acid (PLGA). Additionally,

Art Unit: 1645

another adjuvant may be incorporated inside the microspheres together with the Ag, further enhancing or modulating the immune response. Tetanus toxoid and Hib conjugated to TT (Hib-T) is encapsulated inside PLGA microspheres. Additionally, Gerard et al, Pharma. Res. Sep.2002, vol 19, no 9, pages 1330-1336, also teach the invention of claim 1, e.g., Gerard et al disclose mono and multi-valent vaccines of Hib-TT conjugate, diphtheria conjugate, tetanus toxoid, and pertussis toxin in poly (lactate) and poly(lactic-coglycolate) microspheres. The inventions of Groups I-VI also do not contain the same special technical feature. The invention of Group V does not require the use of a capsular or oligopolysaccharide of H.influenzae B as is required by Group I. Claim 1 does not require additional antigens as is required in the method of Group II. The methods of Groups II and III are unrelated, and therefore possess different special technical features, as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. The kit of Group IV differs from the composition of claim 1, e.g, a second immunogenic composition comprising antigens adsorbed onto an adjuvant with a zero point charge greater than 8 are not required by claim 1. Accordingly, Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

SPECIES:

For claims 19-21, 23-26, 29, 31, 32, 44, 45, 47, 54, 55 and 57- applicants must elect the additional antigen to be used, e.g., one or more pneumococcal capsular oligosaccharide or polysaccharide-carrier protein conjugates, etc..

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Art Unit: 1645

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic: 1-19, 26-46, 48, 51, 53. 56-59.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the compositions comprise immunologically, distinct and different antigens.

6. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

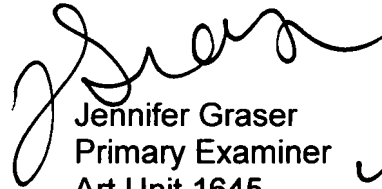
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Application/Control Number: 10/560,513

Page 5

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645

4/27/07